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10/714,489	11/14/2003	Hau H. Duong	A-65682-002	1026
32940 7590 05/31/2007 DORSEY & WHITNEY LLP 555 CALIFORNIA STREET, SUITE 1000 SUITE 1000 SAN FRANCISCO, CA 94104			EXAMINER LU, FRANK WEI MIN	
			ART UNIT	PAPER NUMBER
			1634	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/714,489

Applicant(s)

DUONG ET AL.

Examiner

Frank W. Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-25 is/are pending in the application.
- 4a) Of the above claim(s) 14-16 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-13, 17, 18 and 20-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Response to Amendment***

1. Applicant's response to the office action filed on February 22, 2007 has been entered. The claims pending in this application are claims 11-25 wherein claims 14-16 and 19 have been withdrawn due to species election. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the response filed on February 22, 2007.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. New Matter

Claims 13 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although paragraphs 0022, 0414, 0451, and 0552 of US 2003/0146909 (US Publication of this instant case) suggested by applicant describe the act of analyzing the output waveform for presence of the characteristic waveform includes applying the output waveform to a locked amplifier, paragraphs 0022, 0414, 0451, and 0552 of US 2003/0146909 (US Publication of this instant case) do not indicate that a locked amplifier must be a digital locked amplifier which is

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much narrower than a locked amplifier recited in claim 13. Although paragraph 390 of US 2003/0146909 (US Publication of this instant case) suggested by applicant describes “[T]he AC component may be of variable amplitude and frequency. Generally, for use in the present methods, the AC amplitude ranges from about 1 mV to about 1.1 V, with from about 10 mV to about 800 mV being preferred, and from about 10 mV to about 500 mV being especially preferred. The AC frequency ranges from about 0.01 Hz to about 100 MHz, with from about 10 Hz to about 10 MHz being preferred, and from about 100 Hz to about 20 MHz being especially preferred”, the specification fails to define or provide any disclosure to support the phrase “the input waveform comprises at least a portion having a frequency of about 100 kHz” recited in claim 20 since paragraph 390 of US 2003/0146909 (US Publication of this instant case) suggested by applicant does not specifically describe a frequency of about 100 kHz.

MPEP 2163.06 notes “If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981).” MPEP 2163.02 teaches that “Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.”

### ***Response to Arguments***

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In page 5 seventh paragraph bridging to page 6, fourth paragraph of applicant's remarks, applicant argues that paragraphs 0022, 0414, 0451, and 0552 of US 2003/0146909 (US Publication of this instant case) provide the support for claim 13 while paragraph 390 of US 2003/0146909 (US Publication of this instant case) provides the support for claim 20.

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, although paragraphs 0022, 0414, 0451, and 0552 of US 2003/0146909 (US Publication of this instant case) suggested by applicant describe the act of analyzing the output waveform for presence of the characteristic waveform includes applying the output waveform to a locked amplifier, paragraphs 0022, 0414, 0451, and 0552 of US 2003/0146909 (US Publication of this instant case) do not indicate that a locked amplifier must be a digital locked amplifier which is much narrower than a locked amplifier recited in claim 13. Second, although paragraph 390 of US 2003/0146909 (US Publication of this instant case) suggested by applicant describes "[T]he AC component may be of variable amplitude and frequency. Generally, for use in the present methods, the AC amplitude ranges from about 1 mV to about 1.1 V, with from about 10 mV to about 800 mV being preferred, and from about 10 mV to about 500 mV being especially preferred. The AC frequency ranges from about 0.01 Hz to about 100 MHz, with from about 10 Hz to about 10 MHz being preferred, and from about 100 Hz to about 20 MHz being especially preferred", the specification fails to define or provide any disclosure to support the phrase "the input waveform comprises at least a portion having a frequency of about 100 kHz" recited in claim 20 since paragraph 390 of US 2003/0146909 (US Publication of this instant case) suggested by applicant does not specifically describe a frequency of about 100 kHz.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-13, 17, 18, and 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 11 or 25 is rejected as vague and indefinite. Since the claim does not indicate how difference between the output waveform of an array complex in the presence of a target analyte and the output waveform of an array complex in the absence of the target analyte, it is unclear how analyzing the output waveform of an array complex in the presence of a target analyte can be used as an indication of the presence of a target analyte. Please clarify.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 11-13, 17, 18, 20, 21, 24, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Meade (US Patent No. 6,013,459, filed on June 12, 1997).

Regarding claims 11 and 24, Meade teaches providing an electrode comprising a self

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assembled monolayer (see column 17, lines 23-42) and an assay complex covalently attached to the electrode, the assay complex comprising a target analyte, a capture binding ligand and an electron transfer moiety (see column 1, lines 41-55, column 2, lines 4-10 and claim 1 in columns 24 and 25), applying an input waveform to the electrode, the input waveform eliciting a response of characteristic waveform from the electrode indicative of electron transfer between the electron transfer moiety and the electrode, receiving an output waveform from the electrode, responsive to the input waveform; analyzing the output waveform for the presence of the characteristic waveform as recited in claim 11 and predicting the characteristic waveform based at least on the electron transfer moiety as recited in claim 24 (see column 1, lines 41-55 and columns 21-24).

Regarding claim 12, Meade teaches that the act of analyzing the output waveform includes utilizing chronocoulometry (see column 20, lines 27-44).

Regarding claim 13, Meade teaches that the act of analyzing the output waveform for presence of the characteristic waveform includes applying the output waveform to a digital lock-in amplifier (see column 20, lines 26-44 and column 21, lines 22-33).

Regarding claim 17, Meade teaches that the electron transfer moiety comprises a transition metal complex (see claim 1 in columns 24 and 25).

Regarding claim 18, Meade teaches that the target analyte comprises a nucleic acid (claims 1, 22, and 23 in columns 24 and 25).

Regarding claim 20, Meade teaches that the input waveform comprises at least a portion having a frequency of about 100 kHz (see column 21, lines 55-67 and column 22, lines 1-5).

Regarding claim 21, Meade teaches that the input waveform is a voltage waveform and the output waveform is a current waveform (see claims 11 and 13 in column 25).

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Regarding claim 25, Meade teaches providing an electrode comprising a self-assembled monolayer (see column 17, lines 23-42) and an assay complex covalently attached to the electrode, the assay complex comprising a target analyte, a capture binding ligand and an electron transfer moiety (see column 1, lines 41-55, column 2, lines 4-10 and claim 1 in columns 24 and 25); applying an input waveform to the electrode; receiving an output waveform from the electrode, responsive to the input waveform; analyzing the output waveform using chronocoulometry to identify electron transfer between the electron transfer moiety and the electrode (see column 1, lines 41-55, column 20, lines 27-44, and columns 21-24).

Therefore, Meade teaches all limitations recited in claims 11-13, 17, 18, 20, 21, 24, and 25.

### ***Response to Arguments***

In page 7, second and third paragraph of applicant's remarks, applicant argues that "[C]laims 11 and 25 both recite 'a self-assembled monolayer'. The passage in the '459 Patent (column 17, lines 23-42) cited by the Examiner nowhere discloses 'a self-assembled monolayer'. The '459 Patent therefore does not anticipate claims 11-13, 17, 18, 20, 21, 24 and 25".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. Since monolayer or self-assembled monolayer or SAM is defined as "a relatively ordered assembly of molecules spontaneously chemisorbed on a surface" and the definitions of monolayer and self-assembled monolayer are exchangeable (see the specification, page 14, last paragraph), and Meade providing an electrode comprising a



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monolayer of passivation agent (see column 17, lines 23-42), Meade discloses a self-assembled monolayer.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meade as applied to claims 11-13, 17, 18, 20, 21, 24, and 25 above, and further in view of Mihara *et al.*, (US Patent No. 5,487,032, published on January 23, 1996).

The teachings of Meade have been summarized previously, *supra*.

Meade does not disclose that the characteristic waveform comprises a Gaussian waveform as recited in claim 22.

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Mihara *et al.*, teach to apply a Gaussian waveform to an electrode (see column 3, lines 13-16 and Figure 4).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 22 wherein the characteristic waveform comprises a Gaussian waveform in view of the prior art of Meade and Mihara *et al.*. One having ordinary skill in the art would have been motivated to do so because the simple substitution of one kind of input waveform (ie., the input waveform taught by Meade) from another kind of input waveform (ie., Gaussian waveform taught by Mihara *et al.*,) during the process of performing the method recited in claim 22 or 23, in the absence of convincing evidence to the contrary, would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since the input waveform taught by Meade and Gaussian waveform taught by Mihara *et al.*, are used for the same purpose (ie., serving as an input signal).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

11. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meade in view of Mihara *et al.*, as applied to claims 11-13, 17, 18, 20-22, 24, and 25 above.

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The teachings of Meade and Mihara *et al.*, have been summarized previously, *supra*.

Meade and Mihara *et al.*, do not disclose that the characteristic waveform comprises a modified Gaussian waveform as recited in claim 23.

However, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 23 wherein the characteristic waveform comprises a modified Gaussian waveform in view of the prior art of Meade and Mihara *et al.*. One having ordinary skill in the art has been motivated to do so because optimization of the intensity of Gaussian waveform, in the absence of convincing evidence to the contrary, would have been obvious to one having ordinary skill in the art at the time the invention was made. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to modify the intensity of Gaussian waveform. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Where the general conditions of a claim are disclosed in the prior art, it is not inventive, in the absence of an unexpected result, to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP 2144.05).

### ***Response to Arguments***

In page 7, fourth paragraph bridging to page 8, last paragraph of applicant's remarks, applicant argues that "[T]he '459 Patent does not qualify as a reference under 35 USC 102(a) or 102(b)"; and (2) "[T]he '459 Patent and the claimed invention were, at the time the claimed invention was made owned by the same person. The present Application No. 10/714,489 and US

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Patent 6,013,459 were, at the time the invention of Application No. 10/714,489 was made, owned by Clinical Micro Sensors, Inc. Applicants further note that US Patent 6,013,459 is assigned to Clinical Micro Sensors, Inc. See Reel/Frame 008904/0599 (recorded January 9, 1998). The present application is also assigned to Clinical Micro Sensors, Inc. See Reel/Frame 010831/0634 (recorded May 15, 2000) and 013494/0064 (recorded November 18, 2002).

In view of the above statement of common ownership as well as the referenced assignments, US Patent 6,013,459 is not available as a basis of rejection of claims 22 and 23 under 35 USC 103(a)".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection because there is no evidence to show "the present Application No. 10/714,489 and US Patent 6,013,459 were, at the time the invention of Application No. 10/714,489 was made, owned by Clinical Micro Sensors, Inc" as argued by applicant. Furthermore, the examiner cannot locate an assignment of this instant case.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. No claim is allowed.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

May 25, 2007



FRANK LU  
PRIMARY EXAMINER